Patentability of biotechnological inventions

Plants obtained by essentially biological processes
Patentability of biotechnological inventions

I. EPO and patentability of inventions

II. Focus on EPO
EPO Member States

European Patent Organisation
Founded in 1973
Some 650 million inhabitants
**European member states (38)**
European extension states
Bosnia and Herzegovina
Montenegro
Validation states
Morocco 2015
Moldova 2015
Tunisia – 2017 (TBC)
Cambodia – 2017 (TBC)
I. EPO and patentability of inventions (1)

- The relevant provisions of the EU Biotech Directive 98/44/EC have been incorporated in the Implementing Regulations to the EPC as of 01.09.1999 (by decision of the Administrative Council of 16.06.1999).

- The Biotech Directive is used as a supplementary means of interpretation (Rule 26(1) EPC) for application of the EPC provisions relating to biotechnological inventions.
I. EPO and patentability of inventions (2)

- The case law of the EPO Boards of Appeal and Enlarged Boards of Appeal has provided guidance to take adequate account of technological developments involving biological material.

- CJEU judgments on the interpretation of the Directive are considered as persuasive (see decisions T 2221/10 and T 1441/13 of the EPO Boards of Appeal)
Patentability criteria
(Article 52(1) EPC)

- European Patents shall be granted for any inventions in all fields of technology provided that they are
  - new
  - involve an inventive step and
  - are susceptible of industrial application.

- Some inventions are exempt from patentability.
Ordre public & Morality (Article 53(a) EPC), Article 6 Biotech Directive

- Inventions which commercial exploitation would be contrary to ordre public or morality are exempt from patentability

Essentially biological processes (Article 53(b) and Rule 27(b) EPC), Article 4 Biotech Directive

- Essentially biological processes for the production of plants or animals are exempt from patentability
- This doesn’t apply to a microbiological or other technical process, or a product obtained by means of such a process (bacteria, yeast).
Plant and animal varieties (Article 53(b) and Rule 27 EPC), Article 4 Biotech Directive

- Plant or animal varieties are not patentable

- Plants and animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety (Rule 27(b) EPC).

- Biological material which is isolated from its natural environment or produced by means of a technical process can be patented even if it previously occurred in nature (e.g. plant genes).
Case Law of the EPO Enlarged Board of Appeal on plants

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<tr>
<th>Patentability of plant varieties</th>
<th>(no)</th>
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<td>G 1/98 (1999)</td>
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<th>Patentability of essentially biological processes for the production of plants</th>
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<td>G 2/07 &amp; G 1/08 – &quot;Tomatoes I &amp; Broccoli I&quot; (2010)</td>
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<th>Patentability of products of essentially biological breeding processes</th>
<th>(yes)</th>
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<td>G 2/12 &amp; G 2/13 – &quot;Tomatoes II &amp; Broccoli II&quot; (2015)</td>
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The Commission Notice on certain articles of the Biotech Directive sets out the Commission’s view on the intention of the EU legislators.
- Patentability of products obtained by essentially biological processes
- Compulsory cross-licensing
- Access to biological material

Approved by the Council of the EU and the Parliament
Recent developments at the EPO

- Plants or animals exclusively obtained by means of essentially biological processes are exempt from patentability (new Rules 28(2) and 27(b) EPC)
- Decision of the EPO AC on 29.06.2017
- Application to European patent applications and European patents pending at or after 01.07.2017
- Guidelines for Examination will be adapted accordingly (2017 edition)
- Stayed applications are gradually resumed (OJ EPO 2016, A104)
II. Focus on EPO actions

- EPO/CPVO Administrative Arrangement signed in Munich on 11.02.2016
  - Bilateral workshops, 21-22.09.2016, Angers and 30.03.2017, Munich
  - Overall better understanding of each others system
  - Evaluation of enhanced use of available databases
  - Joint Public Conference in Brussels 29.11.2017
- Special quality systems for sensitive cases handling in examination and opposition (SECA)
- National initiatives to screen patents granted by the EPO
- NGO and media interest
Thank you for your attention!

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European Patent Office, Munich